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**Filed** : **September 30, 2003**

### **REMARKS**

Claims 1-36 and 38-119 were pending, Claims 13, 19-21, 25-27, 34-36, 44, 72-76, 104 and 112 having been withdrawn. With this Response, Claim 65 is canceled and Claims 1, 6, 22, 30, 56, 66, 77, and 85 are amended; therefore, Claims 1-36, 38-64, and 66-119 remain pending for consideration.

### **Election/Restrictions**

The Office Action indicates that Claims 72-76, 104, and 112 were added to the list of withdrawn claims, as they contain subject matter not present in the species of Figure 6, namely, the rotatably coupling of the device to the delivery device, the detachable coupling, and the inflation of the device. Applicant disagrees that these claims should be withdrawn, and respectfully traverses the withdrawal of at least Claims 72-76 and 112, as well as Claims 13, 19, 25 and 34. With respect to the subject matter of Claims 72-76, the portion of the specification relating to Figure 9 describes use of a rotatable plunger to deliver a device such as shown in elected Figure 6. With respect to Claims 13, 19, 25, 34 and 112, the portion of the specification relating to Figure 6 describes use of an inflatable balloon. Accordingly, Applicant submits that Claims 13, 19, 25, 34, 72-76, 104 and 112 should be examined with the elected species.

### **Claim Rejections Under 35 U.S.C. § 112**

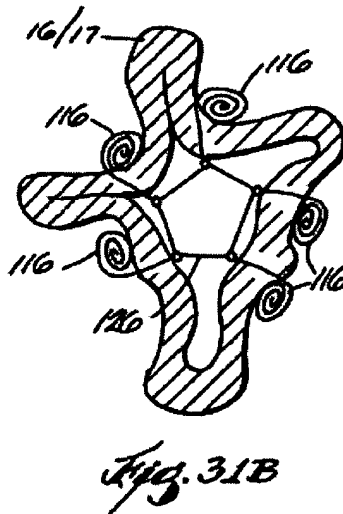
Claims 65-71 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter regarded as the invention. In particular, the Office Action states that in Claim 65 it is unclear if the device being positioned is a different one than the one already positioned in Claim 56 from which Claim 65 depends.

Claim 65 has been canceled and Claims 66-71 now depend directly or indirectly from Claim 56. Applicants therefore respectfully request withdrawal of the rejection under 35 U.S.C. § 112, second paragraph.

**Claim Rejections Under 35 U.S.C. § 102**

Claims 1-12, 14-18, 22-24, 28-33, 38-40, 43, 45-37, 49-71, 77-103, 105-111, and 113-119 are rejected under 35 U.S.C. § 102(e) as anticipated by U.S. Patent No. 5,865,791 to Wayne, et al.

Wayne describes “procedures and devices for *affixing the atrial appendages in an orientation* that reduces subsequent formation of thrombus.” Col. 1, lines 10-12. The Examiner points to a method of closing and occluding a left atrial appendage using an expandable mesh 95. However, the only embodiment disclosed by Wayne for placing the mesh within the interior of the atrial appendage (particularly, without inversion of the LAA) is described in Figures 31A-31C. Figure 31B is reproduced below.



For example, as described at column 12, lines 33-61, a “purse-string-like construction around the interior surface of an appendage . . . enables *pulling of adjacent walls together, thus forming a tightened sack* in which the pouch of the appendage is separated from the remainder of the atrium. . . . To separate the pouch from the atrium, a filler material such as silicone or collagen may be *inserted into the appendage pouch* to fill the pouch and minimize or eliminate blood flow into or out of the pouch. Also, a memory elastic mesh 95 may be *inserted into the pouch or over the sack entrance* for additional support and to prevent thrombus movement from the pouch into the atrium. Also, in this embodiment, *the blood inside the pouch will clot*, forming a naturally occurring support structure for the separated appendage.” (emphases added).

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Claims 1-5 and 50

Claim 1 has been amended to recite, inter alia, “providing a deployment catheter having an implantable device removably carried by the distal end, said device comprising a barrier, said device radially expandable from a reduced diameter to an enlarged diameter and configured to conform to an inside surface of the left atrial appendage,” and “wherein said barrier extends across the left atrial appendage when enlarged and so that at least a portion of the device is in substantial sealing contact with the inside surface of the left atrial appendage.” Wayne fails to teach or suggest providing a catheter having an implantable device that comprises a barrier, let alone a device conforming to an inside surface of the left atrial appendage, a barrier that extends across the left atrial appendage when enlarged, or at a least a portion of the device in substantial sealing contact with the inside surface of the left atrial appendage. Therefore, Claim 1 is patentable over the cited art. Claims 2-5 and 50 depend from Claim 1 and are therefore allowable as well. Claims 2-5 and 50 are also allowable because of the unique combination of features recited therein.

Claims 6-13 and 51

Claim 6 has been amended to recite, inter alia, providing an implantable device having a longitudinal axis and a barrier, wherein the barrier extends across the longitudinal axis when the implantable device is enlarged. Wayne fails to teach or suggest providing an implantable device having a barrier, and further fails to teach or suggest a barrier extending across the longitudinal axis of the implantable device when enlarged. Therefore, Claim 6 is patentable over the cited art. Claims 7-13 and 51 depend from Claim 6 and are therefore allowable as well. Claims 7-13 and 51 are also allowable because of the unique combination of features recited therein.

Claims 14-21 and 52

Claim 14 recites, inter alia, releasing a device from the distal end of a catheter, the device configured to block an opening to the left atrial appendage to prevent passage of embolic material from the left atrial appendage. Wayne fails to teach or suggest releasing a device wherein the device is configured to block an opening to the left atrial appendage to prevent passage of embolic material from the left atrial appendage.

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The mesh 95 described by Wayne, though inserted into the pouch, is not disclosed as blocking the opening to the left atrial appendage, and would not necessarily do so. Rather, Wayne explains that the left atrial appendage opening is constricted by the purse-string arrangement. The mesh 95 merely serves as a support structure within the pouch to prevent thrombus movement from the pouch into the atrium. In addition, Wayne fails to teach or suggest any structure or methodology that would enable positioning of the mesh particularly within the left atrial appendage to block an opening to the left atrial appendage, such as provided by embodiments disclosed in Applicant's specification.

Therefore, Claim 14 is patentable over the cited art. Claims 15-21 and 52 depend from Claim 14 and are therefore allowable as well. Claims 15-21 and 52 are also allowable because of the unique combination of features recited therein.

#### Claims 22-29 and 53

Claim 22 has been amended to recite, inter alia, positioning a device in the left atrial appendage wherein the device conforms to an inside wall of the left atrial appendage when positioned therein. Wayne fails to teach or suggest positioning a device in the left atrial appendage wherein the device conforms to an inside wall of the left atrial appendage when positioned therein. Therefore, Claim 22 is patentable over the cited art. Claims 23-29 and 53 depend from Claim 22 and are therefore allowable as well. Claims 23-29 and 53 are also allowable because of the unique combination of features recited therein.

#### Claims 30-36 and 54

Claim 30 has been amended to recite, inter alia, providing a barrier carried by the implantable device across the left atrial appendage. Wayne fails to teach or suggest providing a barrier carried by the implantable device and further fails to teach or suggest providing a barrier carried by the implantable device across the left atrial appendage. Therefore, Claim 30 is patentable over the cited art. Claims 31-36 and 54 depend from Claim 30 and are therefore allowable as well. Claims 31-36 and 54 are also allowable because of the unique combination of features recited therein.

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Claims 38, 39, 40, 43-46, 49 and 55

Claim 38 recites, inter alia, engaging at least one anchoring element with tissue within the left atrial appendage, the at least one anchoring element being operatively connected to the barrier. Wayne fails to teach or suggest at least one anchoring element being operatively connected to the barrier. Although Wayne mentions the use of an attachment member (see col. 10, lines 45-51 and Fig. 28), the attachment member of Wayne is not operatively connected to a barrier. Therefore, Claim 38 is patentable over the cited art. Claims 39, 40, 43-46, 49 and 55 depend from Claim 38 and are therefore allowable as well. Claims 39, 40, 43-46, 49 and 55 are also allowable because of the unique combination of features recited therein.

Claims 56-64 and 66-71

Claim 56 has been amended to recite, inter alia, preventing passage of embolic material from an atrial appendage comprising positioning a device adjacent an opening of the atrial appendage to block the opening, wherein preventing passage of embolic material occurs substantially entirely as a result of said positioning. Wayne fails to teach or suggest positioning a device adjacent an opening to block the opening, and further fails to teach preventing passage of embolic material substantially entirely as a result of positioning a device adjacent an opening of the atrial appendage. As discussed above, the only embodiment disclosed by Wayne for placing the mesh within the interior of the left atrial appendage is in combination with use of the purse-string-like construction to form a tightened sack. Therefore, Claim 56 is patentable over the cited art. Claims 57-64 and 66-71 depend from Claim 56 and are therefore allowable as well. Claims 57-64 and 66-71 are also allowable because of the unique combination of features recited therein.

Claims 77-84

Claim 77 has been amended to recite, inter alia, positioning an implantable structure adjacent the opening of the atrial appendage wherein the structure conforms to an inner wall tissue surface when enlarged. Wayne fails to teach or suggest positioning an implantable structure adjacent the opening of the atrial appendage wherein the structure conforms to an inner wall tissue surface when enlarged. Therefore, Claim 77 is patentable over the cited art. Claims

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78-84 depend from Claim 77 and are therefore allowable as well. Claims 78-84 are also allowable because of the unique combination of features recited therein.

Claims 85-91

Claim 85 has been amended to recite, inter alia, placing at least a portion of the implantable structure in substantial sealing contact with a tissue surface adjacent the opening of the atrial appendage. Wayne fails to teach or suggest placing at least a portion of the implantable structure in substantial sealing contact with a tissue surface adjacent the opening of the atrial appendage. Therefore, Claim 85 is patentable over the cited art. Claims 86-91 depend from Claim 85 and are therefore allowable as well. Claims 86-91 are also allowable because of the unique combination of features recited therein.

Claims 92-96

Claim 92 recites, inter alia, providing an implantable structure having an enlarged configuration, the enlarged configuration blocking the opening of the atrial appendage. Wayne fails to teach or suggest an enlarged configuration of an implantable structure blocking the opening of the atrial appendage. Therefore, Claim 92 is patentable over the cited art. Claims 93-96 depend from Claim 92 and are therefore allowable as well. Claims 93-96 are also allowable because of the unique combination of features recited therein.

Claims 97-103 and 105-109

Claim 97 recites, inter alia, deploying an implantable structure at the atrial appendage, the structure being configured to block an opening of the atrial appendage. Wayne fails to teach or suggest a structure blocking the opening of the atrial appendage. Therefore, Claim 97 is patentable over the cited art. Claims 98-103 and 105-109 depend from Claim 97 and are therefore allowable as well. Claims 98-103 and 105-109 are also allowable because of the unique combination of features recited therein.

Claims 110, 111 and 113-119

Claim 110 recites, inter alia, positioning a device at the atrial appendage, the device when positioned having at least a portion that generally conforms to an inside surface of the atrial

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appendage. Whayne fails to teach or suggest positioning a device that generally conforms to an inside surface of the atrial appendage when positioned at the atrial appendage. Therefore, Claim 110 is patentable over the cited art. Claims 111 and 113-119 depend from Claim 110 and are therefore allowable as well. Claims 111 and 113-119 are also allowable because of the unique combination of features recited therein.

#### **Claim Rejections Under 35 U.S.C. § 103**

Claims 41, 42, 47, and 48 are rejected under 35 U.S.C. § 103(a) as obvious in view of U.S. Patent No. 5,865,791 to Whayne, et al.

#### **Claims 41, 42, 47, and 48**

Claims 41, 42, 47, and 48 depend from Claim 38, which is patentable over the cited art for the reasons provided above; therefore, Claims 41, 42, 47, and 48 are allowable as well. Claims 41, 42, 47, and 48 are also allowable for the unique combination of features recited therein.

#### **Double Patenting**

Claims 1-12, 14-18, 22-24, 28-33, 38-43, 45-71, 77-103, 105-111, and 113-119 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over Claims 1-29 of U.S. Patent No. 6,152,144 to Lesh, et al. The enclosed Terminal Disclaimer is provided to overcome the double patenting rejection. Withdrawal of the double patenting rejection is respectfully requested.

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**CONCLUSION**

In view of the foregoing amendments and remarks, Applicant submits that this application is in condition for allowance and such action is respectfully requested. If any issues remain or require further clarification the Examiner is respectfully requested to call Applicant's counsel at the number indicated below in order to resolve such issues promptly.

Please charge any additional fees, including any fees for additional extension of time, or credit overpayment to Deposit Account No. 11-1410.

Respectfully submitted,

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Dated: 2/23/06

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